

Patent claims:

1. A process for detecting or determining a C-peptide-containing impurity in a sample of recombinantly produced human insulin or a derivative thereof, by a non-radioactive assay, comprising the steps:

- 5 (a) preparing a sample of recombinantly produced human insulin or a derivative thereof;
- (b) mixing the samples with dilution buffer;
- (c) adding a tracer to mixture (b);
- (d) adding antibody specific for the C-peptide impurity to mixture (c);
- 10 (e) adding "C-peptide second antibody bead" having at least one label to mixture (d); and
- (f) detecting or determining the presence of the C-peptide-containing impurity.

15 2. The process according to claim 1, wherein the C-peptide-containing impurity is C-peptide, preproinsulin or a derivative thereof, or a C-peptide containing insulin or a derivative thereof.

3. The process according to claim 1, wherein the process is performed at a pH of about 8.5 to about 9.0.

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4. The process according to claim 1, wherein the antibody specific for the C-peptide recognizes monkey C-peptide.

25 5. The process of claim 1, wherein the antibody is chosen from:

Z2127, 99Ser1_SD2/F17-22;

Z94, 99Ser2_SD2/P3;

S95-11, 99Ser7/SD2-650/F17-22;

S95-11, 99Ser8/SD2-651/F17-21;

30 S95-11, 99Ser9/SD2-652/F17-24;

S95-11, 99Ser10/SD2-680/F15-25;

S95-11, 99Ser11/SD2-681/F15-24; or

S95-11, 99Ser12/SD2-682/F15-24.

sub
A4

add
A5